Medtronic
XOMED

K000728

MAR 21 2000

**510(k) Summary**

**1.0 Date Prepared:** February 11, 2000

**2.0 Submitter (Contact):**

David Timlin
Medtronic Xomed
Jacksonville, FL
(904) 279-7532

**3.0 Device Name**

Proprietary Name: Medtronic Solan Fiberoptic Corneal Light Probe

Common Name: fiberoptic surgical light

Classification Name: Light, surgical fiberoptic

**5.0 Device Classification**

Fiberoptic Surgical Light

| | | | |
|---|---|---|---|
| Procode FST | Class II; | 21 CFR 878.4580 | Tier 1 |

**6.0 Device Description**

The proposed Fiberoptic Corneal Light Probe is a hand-held surgical field illumination device. The hand-held portion of the device consists of an optical fiber encased in a handle terminated with a stainless steel probe. The probe supports the optical fiber and allows the direction of illumination to the desired position in the surgical field. The cable is terminated on the proximal end with a connector for attachment to an appropriate halogen or xenon light source. An ACMI adapter may be required for connection to light sources with ACMI ports.

The proposed Fiberoptic Corneal Light Probe is supplied in two distal tip configurations. The blunt ended Standard Fiberoptic Corneal Light Probe illuminates the surgical field with a more diffuse light pattern and the Siepser Fiberoptic Corneal Light Probe, which terminates with a hooded-tip, allows the light beam to be directed more precisely to illuminate the surgical field and corneal tissues.

## 7.0 Intended Use

The Fiberoptic Corneal Light Probe is indicated for use in ophthalmic surgical procedures to illuminate the surface of the eye, particularly the cornea, to facilitate the visual examination of ocular tissue. The device may be used in conjunction with procedures such as LASIK surgery to examine the surgical flap (i.e. for orientation, striation and debris).

## 8.0 Substantial Equivalence

The Medtronic Solan Fiberoptic Corneal Light Probe is substantially equivalent with respect to the design, materials and manufacturing processes to the Ophthalmic Light Pipe and Pick manufactured by Escalon Trek Medical Corporation. The Escalon Light Pipe and Pick was cleared for market in 510(k) #K875195.

The only differences in the proposed device and the predicate device are with respect to labeling. The differences in device use, as stated in the labeling of the predicate and proposed devices, present no new issues of safety or efficacy. The intended use of the proposed Fiberoptic Corneal Light Probe actually presents less risk to the patient than that of the predicate, since its use is limited to extraocular illumination of the eye. When used as intended, the proposed device does not come in contact with the patient. The predicate device is intended for intraocular illumination and direct contact manipulation of ocular tissues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 21 2000

Medtronic Xomed
c/o Ms.Carole Stamp
TÜV Product Service
1775 Old Highway 8
New Brighton, Minnesota 55112-1891

Re: K000728
Trade Name: Fiberoptic Corneal Light Probe
Regulatory Class: II
Product Code: FST
Dated: March 3, 2000
Received: March 6, 2000

Dear Ms. Stamp:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**510(k) Number** (if known): K000728
**Device Name:** Fiberoptic Corneal Light Probe

**Indications for Use:**

The Fiberoptic Corneal Light Probe is indicated for use in ophthalmic surgical procedures to illuminate the surface of the eye, particularly the cornea, to facilitate the visual examination of ocular tissue. The device may be used in conjunction with procedures such as LASIK surgery to examine the surgical flap (i.e. for orientation, striation and debris).

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X Or Over-the-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices K000728
510(k) Number